

Summary of Safety and Effectiveness

Device Description

The Hitachi EUB-5500 Diagnostic Ultrasound Scanner is a Track 3 Diagnostic Ultrasound Pulsed Doppler and Pulsed Echo Imaging System capable of the following operating functions:

B Mode

M Mode

Pulsed Doppler

Continuous Wave Doppler

Color Flow

Amplitude Doppler

It is also intended for Harmonic Imaging, Superficial Musculoskeletal Imaging, and 3D Imaging.

Safety

As a Track 3 ultrasound device, the Hitachi EUB-5500 Diagnostic Ultrasound Scanner complies with the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (1992) – published by NEMA as UD-3.

With respect to limits on acoustic outputs, the Hitachi EUB-5500 Diagnostic Ultrasound Scanner complies with the quideline limits set in the 510(k) Diagnostic Ultrasound Guidance – Revision: April 14, 1994.

With regard to general safety, the Hitachi EUB-5500 Diagnostic Ultrasound Scanner is designed to comply with IEC 606601-1 (1998) Medical Electrical Equipment, Part 1 - General Requirements for Safety.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

AUG 2 2 2003

Hitachi Medical Corporation % Mr. Doug Thistlewaite Manager, Regulatory Affairs Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park TWINSBURG OH, 44087

Re: K032503

Trade Name: Hitachi EUB-5500 Ultrasound Scanner

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

R'egulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: 90 IYN, IYO, and ITX

Dated: August 6, 2003 Received: August 13, 2003

Dear Mr. Thistlewaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Hitachi EUB-5500 Ultrasound Scanner, as described in your premarket notification:

Transducer Model Number

EUP-B514 EUP-C514 EUP-C532 EUP-ES52M EUP-F531 EUP-L53S EUP-L54M EUP-O53T EUP-OL334 EUP-R54A-19 EUP-S50 EUP-TC3 EUP-U533 EUP-V53W

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

System:

EUB-5500

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application					de of Operation		
General	Specific	В	M	PWD	CWD	Color	Combined*	Other**
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)
Ophthalmic	Ophthalmic							
	Fetal	N	N	N	N	N	N	N
	Abdominal	Na,b	Na,b	Na,b	N	Na,b	Na,b	Na,b
	Intra-operative (Spec.)	Nc,d_	Nc,d	Nc,d		Nc,d	Nc,d	Nc,d
	Intra-operative (Neuro.)	N	N	N		N	N	N
	Laparoscopic	N	N	N		N	N	N
	Pediatric	N	N	N	N	N	N	N
	Small Organ (Spec.)	Nd,e	Nd,e	Nd,e		Nd,e	Nd,e	Nd,e
	Neonatal Cephalic	N	N	N		N	N	N
Fetal Imaging & Other	Adult Cephalic	N	N	N	N	N	N	N
	Trans-rectal	Nf,h	Nf,h	Nf,h		Nf,h	Nf,h	Nf,h
	Trans-vaginal	Ng	Ng	Ng		Ng	Ng	Ng
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N	N	N		N	N	N
	Musculo-skel. (Superfic.)	N	N	N		N	N	N
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	N	N	N	N	N	N	N
	Cardiac Pediatric	.N	N	N	N	N	N	N
	Trans-esophageal (card.)	N	N	N		N	N	N
	Other (spec.)							·
Peripheral	Peripheral vessel	N	N	N	N	N	N	N
Vessel	Other (spec.)							

N = new indication.

Additional Comments:

Subscript "a":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
Subscript "b":	Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures
	(including amniocentesis).
Subscript "c":	Includes imaging of organs and structures exposed during surgery
	(excluding neurosurgery and laparoscopic procedures).
Subscript "d":	Includes thyroid, parathyroid, breast, scrotum, penis.
Subscript "e":	Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
Subscript "f":	Includes imaging for guidance of transrectal biopsy.
Subscript "g":	Includes imaging for guidance of transvaginal biopsy.
Subscript "h":	Includes imaging for guidance of trans-perineal biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Of) Division of Reproductive, Abdominal, ENT

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System:	
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EUB-5500

Transducer:

EUP-B514

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Intended use: Diagnostic ultrasound imaging or fluid now analysis it the fluid and obey as in								
	В	M	PWD	CWD		1 1	Other**	
					Doppler	(Spec.)	(Spec.)	
Ophthalmic								
Fetal	N	N	N		N	N	N	
Abdominal	Nb	Nb	Nb		Nb	Nb	Nb	
Intra-operative (Spec.)	Nc	Nc	Nc		Nc	Nc	Nc	
Intra-operative (Neuro.)							·	
Laparoscopic								
Pediatric								
Adult Cephalic	ļ							
Trans-rectal							·	
Trans-vaginal								
Trans-urethral						1		
			ļ					
			<u> </u>			ļ		
<u> </u>		<u></u>						
Other (spec.)								
Cardiac Adult								
Cardiac Pediatric								
Trans-esophageal (card.)]					
Other (spec.)								
Peripheral vessel								
Other (spec.)								
	Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel	Specific (Tracks I & III) Ophthalmic Fetal N Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel	Specific (Tracks I & III) Ophthalmic Fetal N N N Abdominal Nb Nb Intra-operative (Spec.) Nc Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel	Specific (Tracks I & III) Ophthalmic Fetal N N N Abdominal Nb Nb Nb Intra-operative (Spec.) Nc Nc Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel	Specific (Tracks I & III) Ophthalmic Fetal N N N N Abdominal Nb Nb Nb Nb Intra-operative (Spec.) Nc Nc Nc Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel	Specific (Tracks I & III) Ophthalmic Fetal N N N N N N N N N N N N N N N N N N N	Specific (Tracks I & III)	

N = new indication.

Additional Comments:

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Subscript "h":	Includes imaging for guidance of trans-perineal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Warin A. Symm
(Division Sign Off)
Division of Reproductive, Abdominal, ENT.

and Radiological Devices

510(k) Number 1

|umber: _____

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler and 3D Imaging.

System: EUB-5500
Transducer: EUP-C514

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General	Specific	В	M	PWD	CWD	Color	Combined*	Other**	
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	N	N	N		N	N-	N	
	Abdominal	Nb	Nb	Nb		Nb	Nb	Nb	
	Intra-operative (Spec.)		<u> </u>						
	Intra-operative (Neuro.)								
	Laparoscopic						L		
	Pediatric	N	N	N		N	N	N	
	Small Organ (Spec.)	Ne	Ne	Ne		Ne	Ne	Ne	
	Neonatal Cephalic							·	
Fetal Imaging	Adult Cephalic		<u> </u>						
& Other	Trans-rectal								
	Trans-vaginal		<u> </u>				ļ		
	Trans-urethral		1						
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)						1		
	Musculo-skel. (Superfic.)								
	Intra-luminal								
·	Other (spec.)								
Cardiac	Cardiac Adult				1		<u> </u>	*****	
	Cardiac Pediatric			ļ					
	Trans-esophageal (card.)	L	1	<u> </u>			1		
	Other (spec.)								
Peripheral	Peripheral vessel								
Vessel	Other (spec.)	l		<u> </u>	<u> </u>				

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Qt)
Division of Reproductive, Abdominal, ENT.

Division of Reproductive, Abdominal, I and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System:

EUB-5500

Transducer:

EUP-C532

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	ical Application	Mode of Operation								
		В	M	PWD	CWD	Color	Combined*	Other**		
General	Specific	ь	IVI	FWD	CWD	Doppler	(Spec.)			
(Track I only)	(Tracks I & III)					Doppier	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic						 			
	Fetal									
	Abdominal	N	N	N		N	N	N		
	Intra-operative (Spec.)	N	N	N		N	N	N		
	Intra-operative (Neuro.)									
	Laparoscopic									
	Pediatric	N_	N	N		N	N	N		
Fetal Imaging & Other	Small Organ (Spec.)	Nd	Nd	Nd		Nd	Nd	Nd		
	Neonatal Cephalic	N	N	N		N	N	N		
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
ļ	Intra-luminal									
	Other (spec.)									
	Cardiac Adult			1						
Cardiac	Cardiac Pediatric			1			1			
	Trans-esophageal (card.)				1 1		1			
	Other (spec.)	•			1					
Peripheral	Peripheral vessel	N	N	N	1 1	N	N	N		
Vessel	Other (spec.)									
3.7 : 1:	<u> </u>			<u> </u>	<u> </u>					

N = new indication.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Qf)
Division of Reproductive, Abdominal, BNT.

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler and 3D Imaging.

System:

EUB-5500

Transducer:

EUP-ES52M

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	Diagnostic ultrasound imag	ing or i	ruid Ho	w allaly						
Clin	ical Application	Mode of Operation								
General	Specific	В	M	PWD	CWD	Color	Combined*	Other**		
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal									
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)									
	Laparoscopic									
	Pediatric									
	Small Organ (Spec.)									
Fetal Imaging & Other	Neonatal Cephalic									
	Adult Cephalic		ļ			нач				
	Trans-rectal			ļ		·	1			
	Trans-vaginal			1		·	<u></u>			
1	Trans-urethral									
	Trans-esoph. (non-Card.)		1							
	Musculo-skel. (Convent.)		ļ	1						
1	Musculo-skel. (Superfic.)		ļ			_				
	Intra-luminal			<u> </u>						
	Other (spec.)		<u> </u>							
Cardiac	Cardiac Adult									
	Cardiac Pediatric			<u> </u>						
	Trans-esophageal (card.)	N	N	N	N	N	N	N		
	Other (spec.)									
Peripheral	Peripheral vessel			ļ						
Vessel	Other (spec.)		<u> </u>	<u> </u>			<u> </u>			

N = new indication.

Additional Comments	Additional	Comments
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Reproductive, Abdominal, ENT.

and Radiological Devices

510(k) Number:

K032503

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler and 3D Imaging.

EUB-5500 System: Transducer: EUP-F531

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	Clinical Application		Mode of Operation							
General	Specific	В	M	PWD	CWD	Color	Combined*	Other**		
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic									
	Fetal						•			
	Abdominal	N	N	N		N	N	N		
	Intra-operative (Spec.)	Nc	Nc	Nc		Nc	Nc	Nc		
	Intra-operative (Neuro.)	N	N	N		N	N	N		
	Laparoscopic									
	Pediatric	N	N	N		N	N	N		
	Small Organ (Spec.)	Nd_	Nd	Nd		Nd	Nd	Nd		
	Neonatal Cephalic	N	N	N		N	N N	N		
Fetal Imaging										
& Other	Trans-rectal	N	N	N		N ·	N	N		
	Trans-vaginal	N	N	N		N	N	N		
1	Trans-urethral			<u> </u>		****				
ļ.	Trans-esoph. (non-Card.)			ļ						
	Musculo-skel. (Convent.)						1			
	Musculo-skel. (Superfic.)			1			1			
	Intra-luminal			<u> </u>				J. 100-1		
	Other (spec.)									
	Cardiac Adult			ļ			1			
Cardiac	Cardiac Pediatric		ļ							
	Trans-esophageal (card.)			<u> </u>						
	Other (spec.)									
Peripheral	Peripheral vessel	N	N	N	ļ	N	N	N		
Vessel	Other (spec.)	L								

N = new indication.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures Subscript "b": (including amniocentesis). Includes imaging of organs and structures exposed during surgery Subscript "c": (excluding neurosurgery and laparoscopic procedures). Includes thyroid, parathyroid, breast, scrotum, penis. Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy. Subscript "e": Subscript "f": Includes imaging for guidance of transrectal biopsy. Includes imaging for guidance of transvaginal biopsy. Subscript "g": pt "h": Includes imaging for guidance of trans-perineal biopsy.
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Subscript "h":

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler and 3D Imaging.

System:

EUB-5500

Transducer:

EUP-L53S

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clin	Clinical Application		Mode of Operation							
General	Specific	В	M	PWD	CWD	Color	Combined*	Other**		
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal	Nb	Nb	Nb		Nb	Nb	Nb		
	Intra-operative (Spec.)	_Nc	Nc	Nc		Nc	Nc	Nc		
	Intra-operative (Neuro.)	N	N	N		N	N	N		
1	Laparoscopic									
	Pediatric	N	N	N		N	N	N		
1	Small Organ (Spec.)	Ne	Ne	Ne		Ne	Ne	Ne		
	Neonatal Cephalic									
	Adult Cephalic									
& Other	Trans-rectal					-				
ł	Trans-vaginal									
	Trans-urethral									
1	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)	N	N	N		N	N	N		
	Musculo-skel. (Superfic.)	N	N	N		N	N	N		
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel	N	N	N		N	N	N		
Vessel	Other (spec.)									

N = new indication.

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT

and Radiological Devices

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^{**}Amplitude Doppler and 3D Imaging.

System: EUB-5500
Transducer: EUP-L54M

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

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Clin	ical Application	Mode of Operation								
General	Specific	В	M	PWD	CWD	Color	Combined*	Other**		
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal	Na	Na	Na		Na	Na	Na		
	Intra-operative (Spec.)	Nc	Nc	Nc		Nc	Nc	Nc		
	Intra-operative (Neuro.)	N	N	N		N	N	N		
	Laparoscopic									
	Pediatric	N	N	N		N	N	N		
	Small Organ (Spec.)	Nd	Nd	Nd		Nd	Nd	_ Nd		
	Neonatal Cephalic									
Fetal Imaging	Adult Cephalic									
& Other	Trans-rectal									
	Trans-vaginal						ļi			
	Trans-urethral									
	Trans-esoph. (non-Card.)			1						
	Musculo-skel. (Convent.)	N	N	N		N	N	N		
,	Musculo-skel. (Superfic.)	N	N	N		N	N	N		
	Intra-luminal									
	Other (spec.)	<u> </u>								
	Cardiac Adult									
Cardiac	Cardiac Pediatric			l						
	Trans-esophageal (card.)									
	Other (spec.)									
Peripheral	Peripheral vessel	N	N	N		N	. N	N		
Vessel	Other (spec.)									

N = new indication.

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off

Division of Reproductive, Abdominal, ENP, and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler and 3D Imaging.

EUB-5500

Transducer:

EUP-O53T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

		Mode of Operation							
			T				0.1 44		
	В	M	PWD	CMD		I I	Other**		
					Doppler	(Spec.)	(Spec.)		
Ophthalmic			l						
Fetal									
									
Intra-operative (Spec.)	Nc	Nc_	Nc		Nc	Nc	Nc		
Intra-operative (Neuro.)						1			
Laparoscopic									
Pediatric						ļ.,			
			<u> </u>						
Neonatal Cephalic			1						
Adult Cephalic		<u> </u>							
Trans-rectal		<u> </u>	1						
Trans-vaginal		<u> </u>	<u> </u>						
Trans-urethral			<u> </u>						
Trans-esoph. (non-Card.)									
Musculo-skel. (Convent.)									
Musculo-skel. (Superfic.)		<u> </u>	<u> </u>	ļl					
Intra-luminal		ļ			J				
Other (spec.)									
Cardiac Adult							<u></u>		
Cardiac Pediatric						1			
Trans-esophageal (card.)									
Other (spec.)									
Peripheral vessel									
Other (spec.)			l						
	Specific (Tracks I & III) Ophthalmic Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel	ical Application Specific (Tracks I & III) Ophthalmic Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel	Specific B M (Tracks I & III) Ophthalmic Fetal Abdominal Intra-operative (Spec.) Nc Nc Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel	Specific B M PWD (Tracks I & III) Ophthalmic Fetal Abdominal Intra-operative (Spec.) Nc Nc Nc Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel	Specific Specific Cardiac Pediatric Ca	Specific Specific (Tracks I & III) Specific (Tracks I & IIII) Specific (Tracks I & IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII	Specific B M PWD CWD Color Combined* (Tracks I & III) Ophthalmic Fetal Abdominal Intra-operative (Spec.) Nc Nc Nc Nc Nc Nc Nc Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-urethral Trans-soph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel		

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT.

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler and 3D Imaging.

System:

EUB-5500

Transducer:

EUP-OL334

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

	0	asound imaging or fluid flow analysis if the fluman body as follows.								
Clin	ical Application	Mode of Operation								
General	Specific	В	M	PWD	CWD	Color	Combined*	Other**		
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic									
	Fetal						-			
	Abdominal									
	Intra-operative (Spec.)									
	Intra-operative (Neuro.)			1			<u> </u>			
	Laparoscopic	N	N	N		N	N	N		
	Pediatric		1							
	Small Organ (Spec.)									
	Neonatal Cephalic		<u> </u>							
Fetal Imaging	Adult Cephalic		ļ	1			1			
& Other	Trans-rectal									
	Trans-vaginal		1	_			1			
	Trans-urethral			<u> </u>						
	Trans-esoph. (non-Card.)		į	<u> </u>						
	Musculo-skel. (Convent.)		ļ							
	Musculo-skel. (Superfic.)		<u> </u>		1					
	Intra-luminal			<u> </u>			1			
	Other (spec.)		1							
	Cardiac Adult									
Cardiac	Cardiac Pediatric				li					
	Trans-esophageal (card.)							U-14**		
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.)									
						•				

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT.

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler and 3D Imaging.

EUB-5500 System: EUP-R54A-19 Transducer:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

		Mode of Operation							
	В	M	DWD				Other**		
	ь	101	1 11 1	0""			(Spec.)		
			-		Боррісі	(2,500.)	(орос.)		
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	N	N	N		N	N	N		
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		<u> </u>	<u> </u>						
Musculo-skel. (Convent.)		<u> </u>							
Musculo-skel. (Superfic.)		<u> </u>	<u> </u>						
Intra-luminal			<u> </u>						
Other (spec.)		İ		ļ ļ					
Cardiac Adult									
Cardiac Pediatric									
Trans-esophageal (card.)									
Other (spec.)									
	Specific (Tracks I & III) Ophthalmic Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.)	Specific B (Tracks I & III) Ophthalmic Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal N Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel	Specific B M (Tracks I & III) Ophthalmic Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal N N Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel	Specific B M PWD (Tracks I & III) Ophthalmic Fetal Abdominal Intra-operative (Spec.) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (Spec.) Neonatal Cephalic Adult Cephalic Trans-rectal N N N Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (card.) Other (spec.) Peripheral vessel	Specific	Specific Specific (Tracks I & III) Specific (Tracks I & IIII) Specific (Tracks I & IIIII) Specific (Tracks I & IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII	Specific B M PWD CWD Color Combined*		

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Of) Division of Reproductive, Abdominal, ENT.

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler and 3D Imaging.

System: EUB-5500
Transducer: EUP-S50

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
	Ophthalmic								
	Fetal	N	N	N	N	N	N	N	
	Abdominal	N	N	N	N	N	N	N	
	Intra-operative (Spec.)			<u> </u>					
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	
	Small Organ (Spec.)			<u> </u>					
	Neonatal Cephalic								
Fetal Imaging		N	N	N	N	N	N	N	
& Other	Trans-rectal			<u> </u>					
	Trans-vaginal		!						
	Trans-urethral		ļ	J			<u> </u>		
	Trans-esoph. (non-Card.)		<u> </u>	1			ļ		
	Musculo-skel. (Convent.)		ļ	ļ	11				
	Musculo-skel. (Superfic.)		<u> </u>	ļ				_	
	Intra-luminal		ļ	1					
	Other (spec.)						1		
	Cardiac Adult	N	N	N	N	N	N	N	
Cardiac	Cardiac Pediatric	N	N	N	N	N	N	N	
	Trans-esophageal (card.)		 	ļ					
	Other (spec.)		ļ						
Peripheral	Peripheral vessel	N	N	N	N	N	N	N	
Vessel	Other (spec.)			1					

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT.

and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler, Harmonic Imaging and 3D Imaging.

System:

EUB-5500

Transducer:

EUP-TC3

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

			ing or fluid flow analysis if the numan body as follows:						
Clin	ical Application	Mode of Operation							
General	Specific	_ B _	M	PWD	CWD	Color	Combined*	Other**	
(Track I only)	(Tracks I & III)					Doppler	(Spec.)	(Spec.)	
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative (Spec.)								
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric			<u> </u>					
	Small Organ (Spec.)						ļ		
	Neonatal Cephalic								
Fetal Imaging			l	1			ļ		
& Other	Trans-rectal		<u> </u>	<u> </u>					
	Trans-vaginal			<u> </u>		··-			
	Trans-urethral								
1	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)			<u> </u>		*			
ŀ	Musculo-skel. (Superfic.)								
	Intra-luminal			<u> </u>					
	Other (spec.)		<u> </u>						
	Cardiac Adult		<u> </u>	ļ	N				
Cardiac	Cardiac Pediatric		<u> </u>	<u> </u>	N				
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral	Peripheral vessel				N			······································	
Vessel	Other (spec.)		<u> </u>	<u> </u>			<u> </u>		

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-On)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler.

System: EUB-5500
Transducer: EUP-U533

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic					Боррісі	(Spec.)	(Брес.)	
	Fetal								
	Abdominal								
	Intra-operative (Spec.)								
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric		ļ	<u> </u>					
	Small Organ (Spec.)		<u></u>						
	Neonatal Cephalic		ļ	ļ			1		
Fetal Imaging				L			 		
& Other	Trans-rectal	Nh	Nh	Nh		Nh	Nh	Nh	
	Trans-vaginal				 		ļ		
	Trans-urethral		1	<u> </u>					
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)		ļ	ļ					
	Musculo-skel. (Superfic.)			ļ <u>.</u>					
	Intra-luminal		ļ	ļ			<u> </u>		
	Other (spec.)								
	Cardiac Adult		ļ						
Cardiac	Cardiac Pediatric		<u> </u>	ļ					
	Trans-esophageal (card.)			!					
	Other (spec.)				1				
Peripheral	Peripheral vessel		ļ				<u> </u>		
Vessel	Other (spec.)								

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Add	itional	Comm	ents:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

and radiological Berr

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler and 3D Imaging.

System:

EUB-5500

Transducer:

EUP-V53W

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:									
Clin	ical Application	Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	N	N	N		N	N	N	
	Abdominal						<u> </u>		
	Intra-operative (Spec.)								
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric			!			ļ.,		
	Small Organ (Spec.)								
	Neonatal Cephalic								
	Adult Cephalic								
& Other	Trans-rectal	Nf	Nf	Nf		Nf .	Nf	Nf	
	Trans-vaginal	Ng	Ng	Ng		Ng	Ng	Ng	
İ	Trans-urethral				L1				
1	Trans-esoph. (non-Card.)		ļ	ļ					
	Musculo-skel. (Convent.)								
]	Musculo-skel. (Superfic.)						 		
	Intra-luminal			!					
	Other (spec.)			!					
	Cardiac Adult			ļ	L				
Cardiac	Cardiac Pediatric			!	1		-		
	Trans-esophageal (card.)		ļ	<u> </u>	├ ──		 		
<u></u>	Other (spec.)						1 1	·	
Peripheral	Peripheral vessel			ļ			<u> </u>		
Vessel	Other (spec.)						<u> </u>		

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Of

Division of Reproductive, Abdominal, BNT,

and Radiological Devices

510(k) Number: ___

^{*}Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

^{**}Amplitude Doppler and 3D Imaging.